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EXAMINER	
STROUD, JONATHAN R	

ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,016	NAKAYAMA ET AL.	
	Examiner	Art Unit	
	JONATHAN R. STROUD	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/07/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-21,23-40 and 42-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-21, 23-40, 42-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-21, and 23-50 have been considered but are unpersuasive.

Applicant has amended the independent claims to indicate that the claimed invention is directed towards pores formed only where the stent matrix does not exist.

Applicant further argues there is a lack of motivation to combine and also that the references teach away from combination with each other.

In order to clarify the record, examiner's reasons to combine and the main teachings of each reference will be summarized here.

Dereume 6,165,212, teaches an endoluminal graft with two distinct elements, a metal expandable base 32 and a cover 33 made of polymeric layer coatings, covering all claim limitations as laid out below, and suggests the desirability of fine through pores, for the purpose of treating a diseased or damaged lumen. Dereume teaches procedures of making and other limitations as such.

Dereume speaks both to the desirability of a mesh expandable member covered by a polymeric covering and to the desirability of through pores in such a member.

Edwin further teaches a number of common mandrel techniques known in the art to create a stent with layers of polymeric materials. Edwins is silent on through pores but, as applicant suggests, teaches pores only as a means of bonding differing layers.

McDonald teaches, independent of the structure of McDonald's actual stent, hole patterns and laser perforation of polymeric stent structures in order to create through pores, in any given pattern, in a means applicable to any polymeric layer stent construction.

McDonald does not specifically teach a pattern whereby pores are formed only at the portions where the stent matrix does not exist. However, it is well known in the art that pores created for the purpose of endothelial ingrowth should a) have a higher chance of success if they are not in proximity to a metal or material that can cause an immune system body response, and b) that it is preferable that the pores are not completely covered or blocked by the metallic portions of the stent.

Therefore it would have been obvious to one of ordinary skill in the art to create the fine through pores in a regular fashion only where the stent does not exist.

Applicant freely admits in the specification that JP H11-299901A has fine pores arranged to be spaced substantially equally, but the design does not anticipate the expansion of the stent. It would be will within the skill and obvious to one of ordinary skill in the art to create the fine through pores in a fashion where the expanded geometry of the mesh support will line up with the expanded geometry of the liner. Still further, the independent claims seem to only read on the design of JP H11-299901A, in that the fine through pores need exist only where the stent matrix does not immediately after forming.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 6-21, and 23-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume 6,165,212 in view of Edwin 6,245,099, and further in view of McDonald 6,120,535.

Dereume teaches a stent comprising a tubular stent matrix of which diameter is extendable and a flexible polymer layer coating said stent matrix, [col. 4 l1.13-28, 60-62; further, col. 7 ll 20-21; "if desired, liner.., can be omitted"] said polymer layer is closely attached to and covers the entire surface of the stent matrix [col: 4 ll. 64- 67] stent matrix is a mesh metallic member [col. 10 l1.28-35] polymer layer is provided with a plurality of fine pores [col. 6 l1.24-28, 64-67] fine pores are spaced from each other at intervals of 51 to 10000 microns and each pore has a diameter of 5 to 500 microns [col. 6 l1.24-28], polymer layer is made of segmented polyurethane [col. 6, l1.64-68], polymer layer is a polymer film of silicone series [col. 10 l1.34-38], the thickness of said polymer layer is from 10 to 100 microns [col. 13 ll. 5-7], is coated With a biodegradable polymer [col. 10 ll. 35-40], polymer contains a drug selected from a group consisting of heparin [col. 11 l1.1-6], A stent produced by a process claimed in claim 15 [Fig. 1, 2, 3; col. 4 ll. 13-28].

Dereume further teaches the method where the polymer film for outer layer and the polymer film for inner layer are made of a base polymer only, and after the removal of the mold, the stent matrix with the outer and inner films is impregnated into a liquid resin material of biodegradable polymer so as to form a coating layer of the biodegradable polymer. [col. 1 l1.34-58] the base polymer is a segmented polyurethane polymer [see above] a step of perforating the polymer film on an intermediate product released from the mold [col. 1 l1.45-50]

Dereume further teaches a process comprising a step of forming the polymer film by impregnating a mandrel into a liquid resin material for forming the polymer film and pulling up the mandrel, and a step of equalizing the thickness of the polymer film by pulling up the mandrel in the vertical direction and controlling the pulling up speed. [col. 1 l1.45-50].

Dereume further teaches fine pores formed after the polymer film is formed [col. 6 l1.64-68].

Dereume further teaches a stent comprising stent matrixes, diameter is extendable and polymer films which are attached to both inner and outer peripheries of stent matrixes and have fine pores, stent matrixes aligned longitudinally and are united by the polymer films, the stent matrixes are independent from each other. [col. 4, ll. 13-48,The cover and liner can be joined, and therefore are originally independent from each other]/

Dereume further teaches a stent comprising of stent matrixes which are aligned longitudinally thereof at intervals, a cylindrical outer polymer film which is overlaid on the

outer peripheries, and a cylindrical inner polymer film which is laid on the inner peripheries, [col. 4 l1.13-48], stent matrixes are united by the outer" polymer film and the inner polymer film [col. 4 l1.63-68], the outer polymer film and the inner polymer film allow the shift of the stent matrixes relative to the polymer films during expansion of the stent matrixes [col. 6, ll. 38-42], the outer polymer film and the inner polymer film are bonded to each other at portions between adjacent stent matrixes [col. 4, l1.63-68; "This will ... create some bonding between the ... cover and ... liner at openings between the strands or wires of the tubular support"] stent matrixes are mesh metallic members [as above] outer polymer film and said inner polymer film are not bonded to said stent matrixes [col. 4 l1.49-63; liner and cover bond to each other, not matrix] outer and inner polymer film are partially bonded at meshes of the stent matrixes composed of said mesh metallic members [col. 10 ll. 28-35] outer and inner polymer film are bonded in the dot form [col. 4, ll. 63-68; significant "dots" of joined material exists between stent matrices], outer and inner polymer film are partially bonded to said stent matrixes [col. 2, l1.45-50] outer and inner polymer film are bonded to said stent matrixes in the dot form [col. 4 l1.63-68] outer and inner polymer film are flexible polymer films each having fine pores [col. 6 l1.24- 27] at portions where said outer and inner polymer film are not bonded to stent matrixes and outer and inner polymer film are not bonded to each other, spaces between outer and inner polymer film are filled with one or more selected from a group consisting of physiologically active substances [col. 11 l1.1-6].

Dereume further teaches a stent comprising a stent matrix composed of a mesh tube of which diameter is extendable, a cylindrical outer polymer film overlaid on the

outer periphery of said stent matrix, and a cylindrical inner polymer film laid on the inner periphery of said stent matrix [Fig. 1, col. 4, l1.13- 63], outer and inner polymer film are not bonded to stent matrix and are bonded to each other at least at some of meshes of said mesh stent matrix [col. 4 ll. 49- 63], outer polymer film and said inner polymer film are bonded to each other in the dot form [col. 4 ll 63-68], the bonded portions are perforated [col. 6, l1.64-68] outer polymer film and said inner polymer film are flexible polymer films having fine pores [col. 6, l1.64-68] at a portion where outer and inner polymer film are not bonded to each other, a space between said outer polymer film and said inner polymer film is filled with one or more selected from a group consisting of physiologically active substances [col. 11 l1.1-6] films are coated with a biodegradable polymer [col. 10 l1.28-39] biodegradable polymer contains a drug selected from a group consisting of heparin [col. 11 l1.1-6], fine pores are spaced from each other at intervals of from 51 to 10000 microns [col. 6 l1.24-28, 64-67], each pore has a diameter of from 5 to 500 microns [col. 6 l1.24-28], polymer films are made of segmented polyurethane [col. 6, l1.64-86], the thickness of said polymer films is from 10 to 100 microns [col. 13 l1.5-7], polymer films are coated with a biodegradable polymer [col. 10 l1.28-39], biodegradable polymer contains a drug selected from a group consisting of heparin [col. 11 ll. 1-6].

Dereume fails to explicitly teach some process steps, such as laser perforation or mandrel rotation, or a complete process whereby the stent is created.

Edwin teaches a process comprising a step of forming a polymer film for outer layer by rotating a mold having a cylindrical inner bore about its axis and also supplying a liquid resin material into the mold; a step of supplying said stent matrix into said mold; a step of forming a polymer film for inner layer by rotating the mold about its axis and also supplying a liquid resin material into the mold; a step of releasing the stent matrix with the films from the mold. [col. 10 ll 59-65]

Edwin further teaches a process comprising a step of inserting a polymer film for inner layer into the stent matrix and overlaying a polymer film for outer layer onto the stent matrix; and a step of welding the respective polymer films to the stent matrix [col. 8 ll. 14-40], the welding is conducted by heating the respective polymer films [col. 8 l1.35-40], The respective polymer films and the stent matrix are pressurized from both sides during the welding, [col. 8 ll. 5-10] by inserting a mandrel to the . polymer film for inner layer and applying pressures to the polymer film for outer layer in radial direction toward the middle line [11.34-40], perforating the polymer film of an intermediate product, formed by welding the polymer films to the stent matrix [11.34-40], the polymer films are tubular [Fig. 4], polymer films are coated with a biodegradable polymer [col. 2, l1.13-19].

Edwin fails to teach laser perforation of the fine through pores.

McDonald teaches laser perforation of fine through pores, col. 11 ll. 25-40, fig. 5, and that the drug included is heparin, col. 12 ll. 39-45.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Dereume in view of Edwin, in order to allow stent compression with minimal force and promote a lower profile, as taught by Edwin, and further in view of McDonald, order to achieve the advantages described in McDonald col. 11 ll. 40-55, "the appropriate size will be achieved throughout any variety of implanted diameters" or constructions of the device.

Further, regarding the claims 34-38, the applicant is respectfully advised that in considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." In re Preda, 159 USPQ 342 (CCPA 1968). In this case, it would have been obvious to one of ordinary skill in the art to weld the devices using high-frequency dielectric heating, Joule heat, supersonic vibration, hot isostatic pressing or heat shrinkable films, instead of a generic "heating" as disclosed by Edwin, since one of ordinary skill would have recognized such methods as being one of the many means available in the prior art for welding, selection of a specific one over another being an obvious matter of meeting the specific requirements of a given application.

Further, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the metals and polymers as claimed, since it has been held by the courts that selection of a prior art material on the basis of its suitability for its intended purpose is within the level of ordinary skill. In re Leshing, 125

USPQ 416 (CCPA 1960) and Sinclair & Carroll Co. v. Interchemica/ Corp., 65 USPQ 297 (1945).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to be significantly porous at evenly-spaced intervals, since it has been held by the courts that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device, and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830,225 USPQ 232 (1984),

Further, the use of a stent expandable in the diametric direction rather than the radial direction is so well known in the art so as to have rendered an entire patent subclass to that effect, namely subclass 623/1.17. Therefore the office takes official notice as to the obviousness of this claimed element as well-known alternative in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774
/Thomas J Sweet/
Primary Examiner, Art Unit 3774